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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,281	06/06/2001	Anthony Viole	FORFLOW.008A	8796

7590

03/09/2004

Knobbe< Martens, Olson & Bear, LLP  
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EXAMINER
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BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

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DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/876,281

Applicant(s)

VIOLE ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on December 22, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 3,13-26,31-37,42,46,49,4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-12,27-30,38-41,43-45,47,48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

Claims 27 –30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant refers the pump speed back to an unspecified patient and an up specified flow rate of the person. Since these parameters vary from person to person, the datum point is indefinite as well as the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 ,2and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Aigner USPN 4,540,402.

See page 3 of the office action mailed 12-31-02

Claims 1, 5, 6, 8 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Marhurkar USPN 4,134,402.

See page 4 of the office action dated 12-31-02

Claims 1, 11, 12 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant USPN 5,618,267.

See page 4 of the office action dated 12-31-02

Claims 1-2, 4, 6-8, 12, 38-41, 43-45, 48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Runge USPN 5,785,686.

Runge teaches a catheter with first and second distal ends with a first end being shown at 11a and the second being at location 12 at its tapered end. Runge has several apertures, extending from the distal end to "near" the proximal end. These apertures will also draw or deliver fluids to aid in perfusing (depending on how the device is inserted into the body) in the same fashion as applicant's means and are thus considered equivalents. The catheter is connected to a pump by inflow and outflow conduits 3 and 4. The catheter is fully capable of performing applicant's statements of intended use, which statements are otherwise given little or no patentable weight. The examiner considers the branch portion of the catheter to be a y-connector and to serve as an indicator when inserting the catheter. The examiner notes that the Runge catheter is capable of being operated without inflating the balloons.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Runge. Applicant's relation to the stated persons flow rate is considered indefinite as explained above. The flow rate of the Runge device, if it is set to a specific rate, will inherently be less than some people and would meet the claim. Alternatively, to have provided the pump with a flow control to adjust the rate to a various people would have been notoriously old and well known since pumps are conventionally equipped with such.

Claims 5, 9-11, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Runge. Applicant differs from Runge in reciting a tapered tip at the first distal end, a radiopaque marker and a j-tip. Arguably the Runge reference shows a J- configuration, however it is believed that the claim is limited to preformed tips. Nevertheless, each of these elements are conventional items for assisting the insertion of the catheter into the body and to have included such configurations to Runge to aid in inserting it into the heart would have been obvious.

***Response to Arguments***


Applicant's arguments filed 12-22-03 have been fully considered but they are not persuasive. Applicant's functional language with respect to the catheter claims does not adequately define over the references simply because it depends on what one calls the "cannulation site". Certainly if one calls the point of entry (incision) the cannulation site, the applied references still meet the claim. Likewise, one could consider the points adjacent to the ports to be the cannulation site for claim 50. Applicant is again relying upon unspecified body regions and parameters that offer little distinguishing structure to the claims. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

MWB

March 4, 2004

  
MARK BOCKELMAN  
PATENT EXAMINER